

DIRECTIONS FOR USE

COMPOSITION

The instrument is made of an Annealed Heat Treated (AHT) nickel-titanium alloy brand named Fire-Wire[™]. All files are constant tapered.

EdgeFile[®]X7 Indications for Use

These files are used in endodontics for the removal of dentine and root canal shaping. It is compatible with most rotary file systems, electric motors and handpieces.

Contraindications

- Like all mechanically driven endodontic instruments they should not be used in cases with very severe and sudden curvatures.
- This product contains nickel and should not be used for individuals with known allergic sensitivity to this metal.

Warnings

- A rubber dam system should be used.
- The EdgeFile[®]X7 files are non-sterile and must be sterilised before patient use.
- EdgeFile[®]X7 files are intended for single use only to avoid file separation.
- Rotary motors: The EdgeFile[®]X7 can be used in a clockwise rotary motor but not in the reciprocating motor, which moves in the counter-clockwise direction.

Precautions for Use

As with all products, use carefully until you become proficient with use. Always determine working length using radio graphs and/or apex locator to properly use rotary files. Important points to remember:

1. Use only in an electric motor and handpiece designed for rotary file instruments.
2. Straight-line access is imperative for proper rotary file use and endodontic treatment.
3. Do not force the files down canals, use minimal apical pressure.
4. Clean the flutes frequently and at least after removing the files from the canal.
5. Irrigate and lubricate the canal frequently throughout the procedure.

6. Take each rotary file to length only one time and for no more than one second.

7. In apical areas and curved canals exercise caution.

8. EdgeFile[®]X7 files are single patient use devices.

9. Reuse: Once a file is used do not reuse. If a file is reused and used on a different patient infection can be introduced. Performance of the file can also be reduced.

10. When instrumenting the canal, do not over enlarge the coronal portion of the canal.

11. Too large a file taken to length increases the risk of canal transportation and file separation.

12. EdgeFile[®]X7 files undergo our proprietary Annealed Heat Treatment (AHT) forming our branded Fire-Wire[™] NiTi which increases cyclic fatigue resistance and torque strength. With this proprietary processing, EdgeFile[®]X7 files may be slightly curved. This is not a manufacturing defect. While the file can be easily straightened with your fingers, it is not necessary as once they are inside the canal, EdgeFile[®]X7 files will follow and conform to the natural canal anatomy and curvatures.

Adverse Reactions

- Device fracture/breakage
- Infection
- Complications usually associated with endodontic procedures including:
 - Pain
 - Instrument fracture/breakage
 - Soft tissue damage/bleeding

INSTRUCTIONS FOR USE

Sterilisation

Files must be cleaned and sterilised before use.

• Scrub the instruments with a long-handled bristle brush in water and a suitable detergent (specified for the purpose).

• Rinse thoroughly with distilled, deionized or RO water.

• Allow to air dry.

• Place the instruments, wrapped or unwrapped, in an autoclave tray.

• Insert in a steam gravity cycle autoclave at 134°C-137°C with a max temp of 140°C for a minimum 3 minutes.

• EdgeFile[®]X7 files are for single patient use.

- Used files should be disposed of in a Biohazard Sharps container.

Electric Handpiece

The EdgeFile®X7 file can only be used in an electric handpiece and motor designed for rotary files. See manufacturer specifications.

EdgeFile®X7 Straight-Line Access and Glide Path Formation

- Prepare straight-line access to all canal orifice.
- With lubrication in the canal form a glide path with a size #10 and #15 hand files or mechanical glide path 2/3 down the length of the canal.

EdgeFile®X7 Size Selection: 20 Series (20/.04), 25 Series (25/.04), 30 Series (30/.04), 35 Series (35/.04), 40 Series (40/.04), and 45 Series (45/.04)

- Take #10 hand file to length.
- Take glide path to length. If glide path feels tight resistance then use the steps below.
- Small Canal: Use a 25/.04 then a 20/.04 and repeat until desired file is to length.
- Medium Canal: Use a 35/.04 then a 30/.04 and repeat until desired file is to length.
- Large Canal: Use a 45/.04 then a 40/.04 and repeat until desired file is to length.

Safe Unwinding

- As a safety feature the files are designed to unwind. They may be used until the files unwind backwards.

EdgeFile®X7 Canal Shaping and Cleaning: S1, S2 and SX Files

- With lubricant in the canal and with light apical pressure take the S1 17/.06 into the canal and follow the glide path using an in-and-out motion while laterally brushing the dentine on the outstroke to enhance the straight-line access of the canal.
- Continue shaping with the S1 until resistance is met or 2/3 down the canal is reached.
- Then use the S2 17/.04, in the same way until resistance is met or 2/3 down the canal is reached.
- Switch between the S1 and S2 following the glide path using the same in-and-out as described for both files until 2/3 down the canal is reached.

- Now that the coronal 2/3 of the canal is shaped, form a glide path with the size #10 and #15 hand files or mechanical glide path files into the apical 1/3.
- Establish working length with radiographs and/or an apex locator. Then confirm patency by taking the #10 hand file 1mm past the working length.
- Then, using the same motion as before, switch between the S1 17/.06 and S2 17/.04 until S2 reaches the working length.
- If a larger coronal shape is desired, use the SX 25/12 at any time after the coronal 2/3 is shaped.

Completing Canal Shaping and Cleaning: F1, F2, F3, F4 Files.

- With lubricant in the canal and with light apical pressure complete canal shaping and cleaning by taking the F1 20/.06 down the canal until the working length is reached.
- Apically gauge the foramen at the working length with a #20 hand file. If the #20 hand file is snug at the working length, the canal is shaped and ready to obturate.
- If the #20 hand file is loose, take the F2 25/.06 to the working length, then gauge with a #25 hand file. When necessary, the F3 30/.06 or F4 40/.06 may need to be used.

Obturation of Canal Systems

- When using a thermal carrier system, use size verifiers to determine the proper sized carrier.
- When using a master gutta percha cone that matches the largest file taken to length, remember sometimes you may need to drop down in cone tip size if the corresponding gutta percha to your final rotary file does not go to length.

Speed and Torque

- Use the same handpiece with the same speed and torque settings you are currently using with your rotary system. Or if you wish, you can use all EdgeFile®X7 rotary files at the following speed and torque setting:

Speed	Torque
500rpm	410g cm

Storage

Store at room temperature of 10°C~37.8°C, away from any sunlight.